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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE FIBROGEN, INC., SECURITIES LITIGATION	No. 3:21-cv-02623-EMC **CLASS ACTION** **OMNIBUS OPPOSITION TO MOTIONS TO DISMISS CORRECTED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** Hearing Date: April 28, 2022 Time: 1:30 pm JUDGE: Hon. Edward M. Chen COURTROOM: 5 – 17th Floor

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Whether the Consolidated Complaint alleges facts that, considered holistically, state claims under §10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5, and §20(a) of the Securities Exchange Act, 15 U.S.C. §78t(a).

I. INTRODUCTION[1]

FibroGen is a pharmaceutical company whose financial future depended on the success of its single most important drug, an experimental anemia pill for kidney patients called Roxadustat, which comprised nearly 100% of the Company's annual revenues. FibroGen sought to develop Roxadustat as an alternative to the existing standard of care, a drug called Epogen, which had a significant drawback: it caused serious adverse cardiac side effects in patients. Defendants made clear that if Roxadustat's Phase 3 trials could establish similar efficacy as Epogen without the same safety risks, FibroGen could gain FDA approval for Roxadustat and thereby access a highly lucrative $3.5 billion market that included less-severe chronic kidney disease ("CKD") patients, for whom Epogen was not recommended precisely because of those serious safety issues.

Thus, throughout the Class Period[2]—on every earnings call, and at every investor conference—Defendants emphatically assured investors that Roxadustat's Phase 3 trial results were so "outstanding," "robust" and "extremely clean" that they demonstrated "compelling evidence confirming [R]oxadustat's cardiovascular safety" that was "superior to [Epogen]." Defendants even went so far as to underscore that the drug's safety data had shown a significant "reduction in [cardiovascular] risk" in "incident dialysis" patients, a critical subgroup of less severe CKD patients, which was "huge" and "differentiated" Roxadustat from Epogen. To bolster these assertions, Defendants publicly touted to investors no fewer than nine separate safety analyses of Roxadustat's trial data, each of which not only purportedly confirmed the drug's unprecedented safety, but—because they were supposedly the product of objective, prespecified analyses vetted by the FDA—gave Defendants a "high level of conviction" that the drug would receive FDA approval. Fueled by these assurances, FibroGen's stock price soared by over 46% during the Class Period, reaching as high as $59.91 per share on March 1, 2019, with FibroGen insiders capitalizing through substantial and coordinated insider sales to the tune of over $42 million.

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[1] "¶_" references are to the Corrected Consolidated Class Action Complaint, ECF No. 97 ("CAC" or "Complaint"). "DM" refers to FibroGen, Inc. ("FibroGen" or the "Company"), Conterno, Schoeneck, Eisner and Cotroneo's Motion to Dismiss, ECF No. 106. "YM" refers to Yu's Motion to Dismiss, ECF No. 109. "DX" refers to exhibits to the Kasner Declaration (ECF Nos. 110-111). Unless otherwise stated, all emphasis is added, and all internal quotations and citations are omitted.

[2] The Class Period is from December 20, 2018 through July 15, 2021. ¶2.

However, as was ultimately disclosed, Defendants' representations were utterly false. In reality, and as Defendants themselves would ultimately admit, Defendants had deliberately manipulated each and every one of the nine safety analyses of Roxadustat's trial data to make the drug appear safer than it really was. Indeed, on April 6, 2021, Defendants shocked the market by admitting that the Phase 3 safety results they had repeatedly touted for over two years were not the drug's true data derived from prespecified analyses agreed upon with the FDA, but were falsified data that Defendants had intentionally manipulated "*post hoc*"—meaning that Defendants had changed the data after Defendants already knew the results because the Phase 3 data had been fully unblinded. The FDA has publicly ridiculed this practice as "biased" "data dredging" done in an "attempt to elicit a positive study result from a failed study"—and tellingly, in each of the nine analyses, Defendants had changed the trial data to make Roxadustat appear significantly safer, completely altering the safety profile of the drug. As a result, Defendants were forced to admit that their myriad statements touting Roxadustat as significantly safer than Epogen in the crucial incident dialysis subgroup were nothing more than lies. Based on the real data, Defendants admitted that they "cannot conclude that Roxadustat reduces the risk of . . . [major adverse cardiac events] in incident dialysis [patients] compared to [Epogen]" at all, thus dooming the drug's market prospects. Defendants also admitted that they had not only presented false data to investors, but also to the FDA, as they were forced to "clarify" Roxadustat's New Drug Application ("NDA") to "make sure it was clear [to the FDA] which analyses used which factors, prespecified and *post hoc*." In response to this devastating news, FibroGen's stock price lost 75% of its value, plummeting from a Class Period high of $59.91 per share to only $14.35 per share by the end of the Class Period.

After Defendants' *post hoc* manipulations of Roxadustat's critical trial data were revealed, FibroGen faced a torrent of scathing criticism and outrage over this "staggering admission." Biotechnology market analysts, sophisticated medical journals, preeminent nephrologists and other established industry experts excoriated FibroGen's management for its deception, emphasizing that such *post hoc* changes were no accident, highly material, made the drug appear safe when it clearly was not, and could only have been made by FibroGen's most senior officers. For example, Jefferies emphasized that the real Phase 3 safety data represented "a material change" to Roxadustat's safety

profile, while Raymond James lamented that "[t]he [cardiovascular] safety data we were presented aren't real" and the actual prespecified data were "meaningfully worse than what was presented in the past." Similarly, STAT+, a prominent pharmaceutical news outlet, lambasted FibroGen for "touting false heart safety data for [Roxadustat] for at least two years," underscoring that Defendants' fraud represented "the worst case of data manipulation in years." *FiercePharma*, another major pharmaceutical publication, concluded that "[t]he fact that all nine analyses" had been changed "rais[ed] the suspicion that someone within FibroGen carefully selected the new criteria to make [Roxadustat's] profile look better." Dr. Daniel Coyne, a nephrologist who served as a site investigator for the Roxadustat trials, stated that Defendants' statements concerning the data were "wildly misleading" and concluded: "I don't know how this could happen accidentally." Dr. Geoffrey Porges, a preeminent biotechnology analyst, called FibroGen's admission "nothing less than stunning," emphasizing that "the restatement [of the safety analyses] reduced the benefit from [Roxadustat] vs. controls in every case" and "erased the appearance of superiority over [Epogen] in incident dialysis patients." In addition to this universal condemnation, Defendants' data machinations have now spawned an SEC investigation of FibroGen.[3]

In the face of these damning allegations, Defendants ask the Court to completely ignore their own stark admissions; their blatant *post hoc* manipulations of crucial Phase 3 clinical trial data for a drug that comprised nearly all of the Company's revenue; the collective outrage and shock expressed by analysts and the medical community upon learning that Defendants had deceived them for over two years; and the Individual Defendants' highly suspicious insider selling. Defendants' arguments are meritless and should be wholly rejected.

First, with respect to falsity, Defendants argue that their undisclosed *post hoc* manipulations of Roxadustat's trial data were simply a matter of differing scientific opinions, and that the dozens of statements they made to investors touting the drug's safety were mere puffery. This is nonsense. Indeed, there can be no serious dispute that Defendants have admitted that the safety results they

[3] Specifically, in a February 28, 2022 Form 10-K, FibroGen stated: "In the fourth quarter of 2021, FibroGen received a subpoena from the SEC requesting documents related to [R]oxadustat's pooled cardiovascular safety data. We have been fully cooperating with the SEC's investigation." Available at https://fibrogen.gcs-web.com/node/12451/html.

had been publicly touting for two years were inaccurate, and that Defendants had manipulated each of the nine analyses reported to investors after-the-fact in order to make the drug conveniently appear safer than it really was. Furthermore, Defendants' argument is fatally undermined by the fact that Defendants repeatedly falsely averred to investors that the "outstanding" Phase 3 safety results they presented were based on objective prespecified analyses agreed upon with the FDA, when in fact, those results were the product of Defendants' own *post hoc* manipulations of all nine safety analyses in Roxadustat's favor. Indeed, as analysts and the medical community fully understood—and as even the cases upon which Defendants heavily rely recognize—in order to be reliable, clinical trial data must be analyzed pursuant to prespecified analyses before the data are unblinded or else, as here, "someone can manipulate the unblinded data to obtain a favorable result," thus "raising concerns of . . . fraud." *In re Rigel Pharmaceuticals, Inc. Sec. Litig.*, 697 F.3d 869, 878 (9th Cir. 2012) (cited *passim* in DM). Defendants' *post hoc* manipulations rendered every single statement they made about the Phase 3 data during the Class Period materially false and misleading, as demonstrated by the widespread excoriation by sophisticated market commentators upon Defendants' release of the true data. Significantly, Defendants' motion does not even address this scathing commentary, despite Defendants' repeated attempts to argue that the dozens of statements they made touting the data somehow did not mislead investors.

Second, Plaintiffs' case on scienter could not be stronger. Tellingly, Defendants can provide no non-fraudulent explanation for why they manipulated all nine analyses of the Roxadustat safety data to make the drug look significantly safer than it was, while wholly concealing the real analyses from investors for over two years. Defendants' failure highlights a vital truth: the data could not have manipulated itself. Indeed, it is undisputed that Defendants had in hand the real FDA prespecified analyses (upon which FDA approval depended) that directly contradicted their public statements for the entire Class Period. Rather than reveal those crucial analyses to investors, Defendants flagrantly attempted to pass off their manipulated safety data as truth, and the reason why is obvious: Defendants knew that the real data showed the drug was not safe. Nothing further is needed to establish scienter. While Defendants assert that these allegations are illogical because a company would have no incentive to invest in a drug it knew would not receive FDA approval,

this ignores the critical fact that Defendants here manipulated the data precisely because they sought to deceive not only investors, but also the FDA. As Defendants expressly admitted, because they had submitted misleading information to the FDA, FibroGen was required to promptly "clarify" to the agency the *post hoc* changes they had made. It is undisputed that once the real prespecified FDA analyses were laid bare, Roxadustat was not, and has never been, approved by the FDA.

For these reasons and those set forth further herein, Defendants' motion should be denied.

II. THE COMPLAINT'S ALLEGATIONS[4]

A. FibroGen's Financial Future Heavily Depended On The Success Of The Phase 3 Trials For Its Oral CKD Anemia Drug Roxadustat

FibroGen sought to develop Roxadustat to compete with the prevailing standard of care for CKD patients suffering from anemia, a drug called Epogen. ¶¶39, 40. Thus, in 2013, FibroGen secured an agreement with AstraZeneca ("AZN"), pursuant to which FibroGen was responsible for developing Roxadustat for U.S. commercialization, analyzing its clinical trial data, and presenting that data to the FDA—including Roxadustat's NDA. ¶¶43, 44. In exchange, AZN would provide FibroGen with highly lucrative "milestone" payments, totaling up to $1.6 billion, as developmental and regulatory goals were met—such that, during the Class Period, "substantially all" of FibroGen's revenue was generated from Roxadustat milestone payments. ¶43.

Because Epogen increases the risk of Major Adverse Cardiac Events ("MACE")—thus requiring the FDA's most severe "Black Box" warning—it is only used by severe CKD patients already on dialysis ("DD" patients), and is not recommended for patients who are either not on dialysis ("NDD" patients) or who have just begun dialysis ("incident dialysis" patients). *Id.* FibroGen thus emphasized prior to and during the Class Period that its goal for Roxadustat was to show that it was just as effective as Epogen but had a "more favorable safety profile," thus allowing the drug to capture an estimated $3.5 billion market of these less severe CKD patients. ¶42.

To accomplish this, Defendants told investors that Roxadustat's Phase 3 trials would test

[4] Defendants ask the Court to consider 57 exhibits totaling over 2,200 pages outside the four corners of the Complaint, however as the Ninth Circuit has counseled, the "unscrupulous use of extrinsic documents to resolve competing theories against the complaint" is improper on a motion to dismiss, particularly "in SEC fraud matters, where there is already a heightened pleading standard, and the defendants possess materials to which the plaintiffs do not yet have access." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018).

three key safety endpoints: (i) time to first MACE, meaning how long it would take for a patient on Roxadustat to experience an adverse cardiac event; (ii) all-cause mortality ("ACM"), or deaths caused by the drug for any reason; and (iii) "MACE+," a measure of MACE that includes all MACE events plus hospitalizations for cardiac events. ¶47. The resulting safety data would produce nine separate safety analyses of the drug—MACE, ACM and MACE+ for each of the DD, NDD and incident dialysis populations. *Id.* Significantly, these three endpoints would be measured by what is known as a "hazard ratio"—a metric that compares the length of time to an adverse safety event for patients on Roxadustat versus Epogen or placebo. The smaller the hazard ratio, the safer the drug, with a hazard ratio of 1 showing Roxadustat was "non-inferior" to, or just as safe as, Epogen or placebo. A hazard ratio of below 1 indicated that Roxadustat was safer than Epogen or placebo, and a hazard ratio larger than 1.25—what the FDA had told FibroGen was its contemplated "non-inferiority" threshold for Roxadustat—meant the drug was too unsafe to be approved. ¶48.

B. During The Class Period, FibroGen Released Highly Positive Roxadustat Phase 3 Data That Purportedly Confirmed The Drug Was Safer Than Epogen And Placebo In Key Patient Populations

Throughout the over two-year Class Period, Defendants repeatedly and emphatically assured investors that the Phase 3 data for Roxadustat (i) was derived pursuant to the FDA's objective, prespecified criteria across each of the studied endpoints; and (ii) had unequivocally confirmed the drug's superiority in safety and efficacy to Epogen, solidifying FibroGen's access to a $3.5 billion market. ¶57. For example, in the months leading up to the Class Period, the market eagerly awaited FibroGen's top-line Phase 3 trial results for Roxadustat, with analysts opining that "Roxa could become a base case $2-4 [billion] franchise" if the data showed that the drug was just as effective as Epogen but with "no major [safety] issues." ¶50. Accordingly, during FibroGen's November 2018 earnings call, analysts urged FibroGen to "calm any recent [investor] concerns" by making a statement in December 2018 verifying that the "broad safety" it had observed in the Phase 3 trials was "similar to prior studies" that had shown "balanced" adverse events. ¶50.

On December 20, 2018, the first day of the Class Period, FibroGen delivered exactly what investors had asked for. Specifically, Defendants proclaimed that the preliminary Phase 3 data had shown that Roxadustat had "achieved superiority in efficacy . . . over [Epogen]," and that while the

"pooled" MACE safety data (meaning safety data aggregated across all Phase 3 trials) would not be released until the spring of 2019, the "preliminary safety analyses" of the Phase 3 studies showed "an overall safety profile consistent with the results in prior Roxadustat studies"—meaning that, despite the fact that the Phase 3 trials had tested nearly 10,000 patients globally, the safety data had matched the safety data of much smaller prior trials that had shown no significant issues. ¶51. Defendants' statements had their intended effect: analysts concluded that FibroGen's statements "g[ave] a large picture of safety that should add comfort" for investors, because the Company had confirmed there were "minimal signs of cardiovascular [MACE] risk." ¶52.

In line with these statements, on May 9, 2019, Defendants announced supposedly "positive" top-line "pooled" safety data for Roxadustat, with detailed data to be presented at the upcoming November 8, 2019 ASN Conference. Defendants touted that the data had shown that Roxadustat (i) was just as safe as placebo in NDD patients, "[t]he gold standard for safety"; and (ii) had achieved "[s]uperiority in time to first MACE+ versus [Epogen] in incident dialysis patients," with "a trend toward reduced [MACE] risk for patients on [R]oxadustat." FibroGen's then-CEO Thomas Neff emphasized that the results for the critically important incident dialysis population were especially significant, as they had supposedly shown a "statistically significant advantage over [Epogen]." ¶53. Defendants further verified that the ITT (intention to treat) analysis they had used to assess the top-line data had been discussed with the FDA, that it was "the safety evaluation standard the FDA usually asks for," and that using a "non-inferiority" threshold of 1.3—which the FDA purportedly "commonly applied"—the data had confirmed Roxadustat was safe. ¶54.

Then on August 8, 2019, FibroGen announced that it had held a pre-NDA meeting with the FDA in July 2019, during which the FDA had purportedly fully blessed FibroGen's analyses of the pooled safety data previously announced on May 9, 2019—which Defendants described as a "very good" development that gave them "very high" confidence that FibroGen's "Phase 3 results confirm[ed] [the] cardiovascular safety of Roxadustat." ¶59. Analysts were relieved that the FDA "has indeed agreed, is receptive [and] on board" with the Company's analyses of the data. ¶60.

On November 8, 2019, at the renowned ASN conference, FibroGen presented more detailed safety data purportedly confirming that Roxadustat was (i) "comparable to placebo in [NDD]

patients"; and (ii) had "reduced the risk of MACE by 30%"—a statistically significant margin—in the crucial incident dialysis patient population. ¶61. Defendants also again specifically assured investors these conclusions were based on the "ITT analysis agreed [upon] with the FDA," and had "us[ed] a reference non-inferiority margin of 1.3" that was supposedly sanctioned by the FDA. ¶62. To unequivocally confirm these results were reliable and derived from the FDA's prespecified criteria, Defendants disclosed all nine of the specific hazard ratios for each of the MACE, ACM and MACE+ endpoints across the three study populations—each one of which showed highly favorable hazard ratios of close to 1 or below 1, thus fully supporting Defendants' claims. ¶63.

Upon receiving the news that all nine of the Phase 3 safety analyses were in Roxadustat's favor, analysts sought further reassurance from the Company that the FDA had "sign[ed] off" on the data they had been presented. In response, Defendants staunchly maintained that the FDA had. For example, during a November 11, 2019 investor call following the ASN conference, Defendant Yu assured investors that FibroGen had "been in dialogue with the FDA" for years and had "a very good understanding" of the "analysis of cardiovascular safety" the FDA wanted to see, and made clear that she had "no concern" because "[t]he results that we have presented . . . were based on the agreed analysis plan that we have made with the FDA." ¶64.

On December 23, 2019, FibroGen submitted the Roxadustat NDA to the FDA, with the FDA's final review scheduled for December 20, 2020 (the "PDUFA" date). ¶66. As the PDUFA date approached, Defendants continued to tout Roxadustat's Phase 3 data and their confidence in FDA approval. For example, FibroGen's new CEO Defendant Conterno stated that after he had personally reviewed the Phase 3 MACE data, the data was "extremely clean," "highly compelling," and had demonstrated "safety against what I think is a very high hurdle of placebo" in every MACE category. ¶67. Defendants also continued to repeatedly tout the purportedly "unbelievable" 30% MACE reduction in incident dialysis patients on Roxadustat, emphasizing that these results "differentiated" the drug. ¶68. As late as the fall of 2020, Defendants asserted that their conversations with the FDA about Roxadustat's "excellent data" were going very well, giving FibroGen a "high level of conviction on the overall [NDA] submission" such that the Company "expect[ed], quite frankly, [FDA] approval . . . by the PDUFA date." ¶69.

Fueled by Defendants' myriad of false statements regarding Roxadustat's purportedly astounding Phase 3 data, FibroGen's stock price surged, reaching a Class Period high of $59.91 per share on March 1, 2019—a highly significant increase of over 46% from its opening price of $41 per share on the first day of the Class Period. ¶134. FibroGen insiders wasted no time in taking full advantage, profiting off the Company's artificially inflated stock through coordinated and substantial insider sales of over $42 million. ¶135. Tellingly, FibroGen's former CEO Neff was the largest seller by far, with his sales alone comprising over $32 million of this amount. *Id*.

C. Under Increasing FDA Scrutiny, FibroGen Is Forced To Admit That Defendants Made *Post Hoc* Manipulations To The Phase 3 Data That Made Roxadustat Look Substantially Safer Than It Was—Causing FibroGen's Stock Price To Plummet

FibroGen's fraud began to unravel on November 27, 2020, when the Company abruptly announced the sudden "retirement" of Defendant Yu—FibroGen's CMO who was directly responsible for the Roxadustat data. ¶72. Then, just three weeks later on December 18, 2020, FibroGen announced that the FDA had "extended the review period of the [NDA] for Roxadustat . . . by three months," with a new PDUFA date of March 20, 2021. ¶73.

Although FibroGen attempted to downplay the PDUFA delay, it soon became evident that it was not benign. ¶¶74, 75. On March 1, 2021, FibroGen shocked the market by announcing that the FDA would hold an AdCom to review the NDA for Roxadustat—a negative development so late in the regulatory process. ¶74. In response, FibroGen's stock price fell 32%. ¶75. Faced with this precipitous decline in FibroGen's stock price, Defendant Conterno reassured investors that FibroGen "continue[d] to have confidence in the completeness of the NDA submission and the strength of the [R]oxadustat data," and continued to emphasize the claimed statistically significant MACE results for incident dialysis patients in particular as "some of our strongest data." ¶76.

However, with FDA public scrutiny now assured, Defendants could no longer conceal the truth. On April 6, 2021, Defendants sent shockwaves through the market by admitting that they had made *post hoc* manipulations to each and every one of the nine previously reported safety analyses of Roxadustat. Tellingly—and significantly—in each and every instance, Defendants' manipulations made Roxadustat appear to be significantly better and safer than it really was. ¶¶77,

85. Indeed, the manipulations were so material that Defendants were forced to admit that based on the real "prespecified" data—and despite their prior repeated claims that Roxadustat lowered the MACE risk in the crucial incident dialysis population by 30%—"we cannot conclude that Roxadustat reduces the risk of . . . [MACE] in incident dialysis [patients] compared to [Epogen]" at all. ¶81. Remarkably, Defendants further admitted that they had not only presented the manipulated data to investors, nephrologists and vulnerable CKD patients (such that they had to retract a publication of the data in renowned medical journal *Kidney International*, among others), but also to the FDA in the Roxadustat NDA—and thus had to "promptly . . . clarify this issue with the FDA" to "make sure that it was clear which analyses used which factors, prespecified and *post-hoc*." ¶84.

It is difficult to overstate the magnitude of Defendants' *post hoc* manipulations. Indeed, there is a significant and well-known difference between *prespecified* statistical analyses—which are performed *before* clinical trial data is unblinded—and *post hoc* analyses, which are selective analyses done in hindsight pursuant to cherry-picked criteria after the data has been fully unblinded (*i.e.*, after FibroGen could see which patients received Roxadustat and what their results were under the prespecified analyses). As the FDA has stated, *post hoc* analyses essentially amount to after-the-fact "data dredging" in an "attempt to elicit a positive study result from a failed study," and as such tend to be "biased" by the drug-maker's "desire for success." ¶79. Defendants' *post hoc* changes here were highly material, as Defendants conceded that they had altered critical "stratification factors" which dramatically changed how patients were categorized in the trials—and were in fact so significant that Defendants were required to issue a complete restatement of all nine hazard ratios they had previously disclosed. ¶¶77, 81. As shown by the chart below—which compares Defendants' *post-hoc* manipulated data reported during the Class Period to the actual prespecified FDA data—Defendants manipulated the Roxadustat data to appear much safer than it really was in every single one of the nine separate safety analyses, and to appear over 17% safer

with respect to the all-important MACE endpoint in the crucial incident dialysis population.

Analyses	*Post-Hoc* Manipulated Analysis	True, Undisclosed FDA Pre-Specified Analysis	% Difference
Incident Dialysis			
MACE	0.70 (0.51, 0.96)	0.82 (0.60, 1.11)	**17.14%**
MACE+	0.66 (0.50, 0.89)	0.78 (0.59, 1.02)	**18.18%**
ACM	0.76 (0.52, 1.11)	0.82 (0.57, 1.18)	**7.89%**
Dialysis Dependent			
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)	**6.25%**
MACE+	0.86 (0.74, 0.98)	0.91 (0.80, 1.05)	**5.81%**
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)	**6.25%**
Non Dialysis			
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)	**1.85%**
MACE+	1.04 (0.91, 1.18)	1.07 (0.94, 1.21)	**2.88%**
ACM	1.06 (1.91, 1.23)	1.08 (0.93, 1.26)	**1.88%**

In response to the shocking news of Defendants' data manipulations, FibroGen's share price was virtually halved, falling 45% from $34.64 per share on April 6, 2021 to $18.81 per share on April 8, 2021—representing another staggering $1.45 billion decline in market capitalization. ¶88.

D. FibroGen's Management Is Excoriated By An Avalanche of Market Analysts, High Profile Medical Journals And Members Of The Nephrology Community

In the wake of Defendants' stunning admissions, prominent market analysts, medical journals and respected nephrologists unanimously condemned Defendants' *post hoc* manipulations, and concluded that they must have been carried out by FibroGen's most senior officers.

For example, STAT+, a preeminent life sciences journal, published an article on April 6, 2021 underscoring the material nature of the data manipulations, stating that "[FibroGen] has been touting false heart safety data [for Roxadustat] for at least two years." ¶90. In a follow-on article, the publication called FibroGen's revelations "the worst case of data manipulation in years," and commented: "[H]ow can anyone—investors, physicians, regulators—trust a company that spent nearly two years touting cardiovascular data that turns out to have been falsified?" ¶99. The article also quoted Dr. Daniel Coyne, a nephrologist who served as a site investigator for the Roxadustat trials, as stating that Defendants' Class Period statements about the Phase 3 data were "wildly misleading," and that he no longer trusted FibroGen's management after he and other kidney specialists "were thrown under the bus" when the Company provided them with false data for publication. *Id.* *FiercePharma*—a major pharmaceutical news outlet—similarly commented that

"[i]n a stunning revelation, FibroGen admitted to presenting Roxadustat data manipulated to make the anemia drug look safer than it is." The article concluded that there was no question the manipulations were intentional and orchestrated by senior management, since Roxadustat was "a do-or-die FDA" filing, and "[t]he fact that all nine analyses . . . looked less favorable for [R]oxadustat after the change raises the suspicion that someone within FibroGen carefully selected the new criteria to make [R]oxa's profile look better." ¶95. Similarly, a high-profile article published by ASN emphasized that, tellingly, the "net effect" of FibroGen's "statistical shenanigans" was "to remove [R]oxadustat's evident safety advantage compared with the drugs it would presumably replace." ¶96. The article also quoted Dr. Coyne, who stated that he "fel[t] very misled" and "I don't know how this could happen accidentally." *Id.*

Market analysts also reacted with shock and skepticism at the degree to which the real data was materially worse, and lambasted FibroGen's management for misleading investors. For example, an April 7, 2021 Jefferies report stated that "the fact that Incident Dialysis is no longer 'statistically' superior – is a material change to the profile," as it was "one of the key prior advantages" Roxadustat had over Epogen. ¶91. An April 6, 2021 Raymond James report—aptly titled: "The Roxa Saga Continues: This Episode We Find Out The MACE Data We Were Presented Aren't Real"—stated that the real data looked "meaningfully worse than what was presented in the past," and that FibroGen's credibility was in serious jeopardy, particularly considering that it "had multiple prior opportunities to 'clarify' the dataset with the FDA." ¶93. Dr. Geoffrey Porges, one of Wall Street's most influential biotechnology analysts, called FibroGen's admission "nothing less than stunning," and emphasized that "the restatement [of the safety analyses] reduced the benefit from [Roxadustat] vs. controls in every case, erased the appearance of superiority over [Epogen] in incident dialysis patients, and increased the apparent risk of a negative effect of [Roxadustat] on CV safety in non-dialysis patients." ¶97. Similarly, an April 7, 2021 H.C. Wainwright report also highlighted that Roxadustat's true data was "weaker than the data the company previously announced and published," and noted that the Company's "unfavorable disclosure" erased any safety benefit of Roxadustat over Epogen in incident dialysis patients and "changes our view on [Roxadustat] approvability and potential market uptake." ¶92. Finally, a May 17, 2021

SeekingAlpha article similarly opined that FibroGen's "acknowledged manipulation" of the Roxadustat data was "stark, if not devastating," and concluded that FibroGen's management must have concluded the data "wasn't good enough . . . [s]o they decided to change the 'stratification factors' . . . nearly 2 years ago to make the data look better." ¶100.

E. FibroGen Continued To Fraudulently Withhold Additional FDA Prespecified Analyses Showing Roxadustat Was Not Safe Or Effective For Any Patient Population

Despite the avalanche of criticism, even after Defendants' April 6, 2021 admissions, Defendants continued to claim the safety data showed that Roxadustat was "comparable to placebo in NDD" and "comparable in [DD patients] to [Epogen]." ¶225. However, this was false. Unbeknownst to investors, for the entire Class Period, FibroGen had completely withheld other prespecified FDA "sensitivity" analyses—which the FDA considered to be just as important as the primary analyses—that showed Roxadustat was much more dangerous than placebo and even Epogen. In fact, it was too dangerous to be approved at all, for any patient population.

First, during the July 15, 2021 AdCom, the FDA revealed that despite Defendants' repeated public assurances to investors that Roxadustat was "comparable" to placebo and safer than Epogen based on the FDA's purportedly "commonly applied" hazard ratio threshold of 1.3, in reality, the FDA had flatly rejected the 1.3 threshold during its pre-NDA meetings with FibroGen, and had told FibroGen that it "had a goal of 1.25," not 1.3, for the Roxadustat trials.

Second, the AdCom further revealed that the FDA's mandated prespecified sensitivity analyses—which Defendants had never even mentioned to investors—demonstrated that the hazard ratios in all studied populations exceeded 1.25, meaning Roxadustat was less safe than placebo and even Epogen to a statistically significant degree. Moreover, in the NDD population—which represented the other major portion of the $3.5 billion market FibroGen sought to access—the upper bound hazard ratios for the MACE and ACM endpoints were 1.7 and 1.82, respectively, or approximately 40% and 50% worse than the ratios Defendants had initially presented:

Non-Dialysis Dependent (NDD)			
Endpoint	*Post-Hoc* Manipulated Analysis Reported To Investors	True, Undisclosed FDA Pre-Specified Analysis	True, Undisclosed FDA Pre-Specified "Sensitivity" Analysis
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)	1.38 (1.11, **1.70**)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)	1.40 (1.08, **1.82**)

Based on the numerous alarming and severe safety issues the AdCom found were demonstrated by these sensitivity analyses—including "increased mortality when compared to [Epogen]" despite its Black Box warning, in addition to "sudden cardiac deaths," "serious thromboembolic events," sepsis, stroke, seizures and congestive heart failure—the AdCom panel voted virtually unanimously against approval of Roxadustat for any patient population. ¶112. In so doing, it rejected Defendants' last-ditch effort to save the drug—which, tellingly, was not to assert that Roxadustat was safe, but rather to propose a lower dose of the drug in a desperate attempt to curb its serious adverse events. ¶105. However, as the AdCom concluded, Defendants had never tested Roxadustat at a lower dose—likely because, as panel members surmised, if the dose were lowered Roxadustat could "not match the efficacy of [Epogen]." ¶¶105, 106.

Once again, analysts reacted with dismay, citing the AdCom's "overwhelmingly one-sided vote" against approval based on significant severe safety issues caused by Roxadustat that were "unknown from the company's disclosure to us and to investors before this week." ¶¶115-18. Dr. Porges, a prominent biotechnology analyst, commented that "[w]hen reviewed in the cold harsh light of day," it was apparent that Roxadustat's safety issues were so severe that the drug would never be approved in the U.S. ¶116. In response, FibroGen's stock price plunged again, falling over 42% from $24.84 per share to $14.35 per share on July 16, 2021. ¶113.

III. LEGAL STANDARDS

On a motion to dismiss, courts consider the complaint in its entirety, "accept all factual allegations … as true," and construe them in the light most favorable to the plaintiffs. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007). "[S]o long as the plaintiff alleges facts to support a theory that is not facially implausible, the court's skepticism is best reserved for later stages of the proceedings." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1057 (9th Cir. 2008).

Thus, a plaintiff "need only allege enough facts to state a claim to relief that is plausible on its face." *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 45 n.12 (2011).

IV. ARGUMENT[5]

A. The Complaint Adequately Alleges Defendants' Misstatements And Omissions

A statement is false or misleading "if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Berson v. Applied Signal Tech., Inc*., 527 F.3d 982, 985 (9th Cir. 2008). Once securities issuers "tout positive information to the market, they [are] bound to do so in a manner that wouldn't mislead investors, including disclosing adverse information that cuts against the positive information." *Schueneman v. Arena Pharm., Inc*., 840 F.3d 698, 706 (9th Cir. 2016).

1. Defendants Falsely Claimed That Roxadustat Was Safe Based On After-The-Fact "Data Dredging"—Including That It Was Superior To Epogen And Even Safer Than The "Gold Standard" Placebo

In all nine analyses of the Roxadustat safety data Defendants presented to investors, the scientific community, and the FDA during the Class Period, Defendants manipulated the results to make the drug appear safer than it was. *See* ¶¶77-83. Beginning with Defendants' release of top-line Phase 3 data on December 20, 2018, the first day of the Class Period, Defendants falsely reassured investors that they had observed no significant safety issues with Roxadustat, and then specifically and repeatedly falsely asserted that FibroGen's "Phase 3 results confirmed the cardiovascular safety of Roxadustat"; "CV safety was demonstrated across all studied populations"; the results demonstrated a "statistically significant advantage over [Epogen]" in the crucial incident dialysis population, for which "we showed a 30% reduction in MACE risk"; and that Roxadustat was remarkably comparable to placebo, "the gold standard for safety" that "really illustrated the strength of our drug's safety." *See e.g.,* ¶¶167, 192, 193, 205.[6]

These statements were demonstrably false, based on Defendants' own admission that they

[5] Tellingly, Defendants do not challenge—and thus concede—loss causation, as there is little question that Defendants' fraud badly damaged shareholders, including an almost 75% decline in FibroGen's stock price between February 12, 2021 and July 16, 2021. ¶¶56, 73, 75, 88, 259-68.

[6] *See also* ¶¶143, 147-48, 153, 155, 157-58, 160, 163-65, 167-68, 171-72, 177-79, 181, 184, 187, 189-90, 192-93, 195-96, 199, 201-02, 205, 207-08, 211-12, 217-19.

had manipulated all nine analyses of the safety data after-the-fact to make Roxadustat appear significantly safer than it actually was.[7] ¶¶81, 222-26, 230-31, 233-34. Indeed, Defendants admitted that, based on the real "prespecified" FDA analyses—*i.e.*, the unmanipulated results—"we cannot conclude that Roxadustat reduces the risk of . . . [MACE] . . or is superior to . . . [Epogen]" in incident dialysis patients at all, thus dooming the drug's approval prospects for that lucrative market. Defendants further admitted that they had submitted the manipulated data to the FDA, requiring that FibroGen "promptly . . . clarify this issue with the FDA," and to articles published in multiple prestigious medical journals, which would now have to be retracted. ¶¶84-85. Moreover, Defendants faced a torrent of shock and outrage from the analyst and medical community when the real analyses were revealed, causing a plethora of sophisticated market participants to conclude that Defendants had been "touting false heart safety data [for Roxadustat]"—that was "meaningfully worse" than the data Defendants previously reported—"for at least two years." ¶90. And even after these admissions, Defendants continued to deceive investors by failing to disclose that other prespecified FDA "sensitivity" analyses showed that Roxadustat was so much less safe than Epogen that it could not be approved at all. ¶¶11, 106-11. There is no question that such cold, hard facts demonstrate that Defendants' statements about Roxadustat were materially false and misleading. *Arena*, 840 F.3d at 708 (drug-maker's statements about clinical trial data were false where it "express[ed] confidence by claiming that all of the data was running in [drug's] favor" when "[i]t was not"); *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1021 (S.D. Cal. 2005) (defendants' touting of selective sub-study results while concealing that broader FDA-sanctioned Phase 3 study showed the exact opposite were materially false and misleading).

In their motion, Defendants nonetheless ask the Court to hold as a matter of law that their misstatements misled no one and omitted nothing. Their arguments fail.

First, Defendants' assertions that their positive statements about Roxadustat's safety data were not misleading (*see* DM at 15, 16) are wholly belied by the universal outrage expressed by

[7] *Arena*, 840 F.3d at 708 ("Contrary to [Defendant's] representations to investors, it was not true that the [studies] demonstrated the "long-term safety and efficacy" of [the drug] or "the potential risk that [it] may be toxic or cause cancer in humans." It was also not true…that "everything that [they had] compiled so far" was "favorable").

sophisticated market analysts and members of the medical community, who uniformly concluded that the real prespecified data "looks meaningfully worse" and constituted a "material change" to Roxadustat's safety profile, such that the Company's *post hoc* changes amounted to "the worst case of data manipulation in years." Tellingly, Defendants fail to even address this scathing commentary (as well as the ensuing massive stock price drop), which shows that investors were unquestionably severely misled by Defendants' "data doctoring" and "statistical shenanigans." Indeed, Defendants themselves admitted that, based on the real Phase 3 data results, they could no longer "conclude that Roxadustat reduces the risk of (or is superior to) . . . MACE . . . in incident dialysis compared to [Epogen]" at all—completely reversing a key claim that Defendants had repeatedly told investors was "huge" and "differentiated" Roxadustat. Incredibly, in their motion, Defendants assert that, despite this striking admission, their repeated statements regarding the incident dialysis population were not false because they were supported by the doctored data. DM at 18. However, as Defendants knew, this was meaningless—FDA approval hinged on the prespecified analyses, not Defendants' *post hoc* manipulations, and tellingly, Roxadustat was never approved by the FDA.

Second, contrary to Defendants' attempt to re-write history, their April 6 revelations did not provide mere "additional analyses" showing "slightly different results" that did not change any major conclusions about the data. DM at 17. Indeed, this argument ignores reality, as demonstrated by the numerous comments and remarks of financial analysts, prominent medical journals and nephrologists referenced above—all of whom uniformly concluded that the *post hoc* changes constituted a "material change," were "stunning" and "the worst case of data manipulation in years." Rather than these changes being minor or inconsequential, as stated above, Defendants admitted that, based on the real data, "we cannot conclude that Roxadustat reduces the risk of (or is superior to) MACE . . . in incident dialysis compared to [Epogen]" at all—thus extinguishing a major market for the drug.

Third, Defendants' and Yu's assertions that their statements prior to July 2019 were not false because "it was not until the pre-NDA meeting with the FDA in July 2019 that the FDA and FibroGen reached agreement on the analyses methods"—and that their *post hoc* changes were somehow sanctioned by the FDA because "the entire analytical framework was developed with the

FDA 'post hoc'"—ignores the facts and Defendants' own admissions. DM at 16, 18; YM at 6-10. Defendants flatly admitted on April 6, 2021 that the safety results they had touted for over two years were not the product of analyses agreed upon with the FDA, but rather Defendants' own *post hoc* manipulations—necessitating that all nine hazard ratios be corrected to reflect the real prespecified analyses. This was made evident by Defendants' admission that they had to rush to "clarify" the NDA they had filed with the FDA, which had presented the manipulated data as if it were the real data. Moreover, the data Defendants touted prior to the July 2019 pre-NDA meeting was clearly the manipulated data, as evidenced by the fact that, in May 2019, Defendants proclaimed that the MACE safety data had shown that Roxadustat was safer than Epogen in incident dialysis patients—an assertion Defendants had to reverse because the real data showed the exact opposite.[8]

Fourth, Defendants' claim that the FDA allowed FibroGen to come up with a brand-new statistical analysis of the data *post hoc* is clearly erroneous, as this would completely defeat the purpose of a double-blind trial and fly in the face of FDA guidance instructing that clinical trials analyses must be prespecified. Presumably, if this assertion were actually true, Defendants would not have been forced to "clarify" the NDA that they had submitted to the FDA, and the FDA would not have refused to approve the drug for any patient population whatsoever. Indeed, Defendants admit in their motion that their statistical plans for the trials were submitted to the FDA before the Phase 3 data were unblinded and well before the July 2019 pre-NDA meeting—*see* DM at 4, DX B and C (FibroGen's statistical plans dated August and September 2018)—and Defendants told investors that they had been discussing the statistical analyses with the FDA for the Phase 3 trials for years. ¶64. Thus, the purpose of the pre-NDA meeting was to determine which of these prespecified plans should be used in the NDA, not to doctor the fully unblinded results of those prespecified analyses by changing them *post hoc*—something the FDA would never allow.[9]

[8] Indeed, Defendants expressly admit in their motion that the data they touted in May 2019 used the *post hoc* stratification factors rather than the "prespecified" factors included "in the underlying [statistical analysis plans] for each of the separate studies." DM at 10.

[9] In particular, Defendants' debate with the FDA was whether the "ITT" or "OT+7" analyses should be used as the primary analyses for purposes of the NDA—ITT continues to evaluate the safety of

Finally, Defendants are simply wrong that the FDA agreed that there was "no significant difference in the risk of MACE" between the drug and its comparators in NDD and DD patients. DM at 17. If that were true, the AdCom would not have overwhelmingly voted against the approval of Roxadustat in both of those patient populations. Indeed, while the passage from the AdCom transcript that Defendants misleadingly cite in support of this assertion states that based on the FDA's primary analysis in NDD patients (the ITT analysis) there was "no significant difference" in MACE risk, in the very next sentence the AdCom states that, "[o]n the other hand, the results from the [OT+7] sensitivity analysis"—*i.e.*, the other critical FDA prespecified analysis Defendants misleadingly withheld from investors—"suggest an increased risk of MACE for the Roxadustat arm compared to placebo." DX XX at 169. It was based on these alarming results—which Defendants never so much as mentioned to investors during the Class Period—that the AdCom voted virtually unanimously against approval of Roxadustat for either patient population.[10]

Significantly, Defendants nowhere address that they utterly failed to reveal these prespecified sensitivity analyses to investors, which along with the primary prespecified analyses, directly contradicted Defendants' statements. The complete omission of these highly material analyses alone establishes that Defendants' statements were materially misleading. *Arena,* 840 F.3d at 707-08 (Arena's complete concealment of rat study showing cancer risk of weight loss drug rendered positive statements about safety data materially misleading).

2. Defendants Falsely Claimed That Roxadustat Had Achieved Non-Inferiority By Referencing A Non-Inferiority Margin Of 1.3

Throughout the Class Period, Defendants falsely stated that Roxadustat had achieved non-inferiority because its hazard ratio was below the 1.3 threshold that the FDA purportedly

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patients who take the drug long after they stop taking it, while OT+7 does not. But both analyses were to be conducted pursuant to prespecified stratification factors that were clearly not supposed to be selectively changed by FibroGen after-the-fact to make the results look better.

[10] The cases Defendants cite, which find that immaterial information about clinical trials does not need to be disclosed, are incomparable to Plaintiffs' claims. *See In re MELA Sci., Inc. Sec. Litig.*, 2012 WL 4466604, at *13-14 (S.D.N.Y. Sept. 19, 2012) (pre-*Omnicare* dismissal where criticism of trial's "utilization of an unsound statistical analysis" was immaterial); *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) (denying claim because plaintiff failed to allege that the company's "interpretation of the data was irrational or unreasonable," thus rendering it immaterial). Here, the nephrology community unanimously concluded that Defendants had doctored the data. ¶¶89-100.

"commonly applied," and which the FDA would supposedly be looking for in reviewing Roxadustat's MACE results. *See e.g.,* ¶¶147, 157, 158, 160, 172, 181, 184, 201, 225; *In re MannKind Sec. Actions,* 835 F. Supp. 2d 797, 812 (C.D. Cal. 2011) ("Defendants' statements concerning [] the FDA's pre-approval or 'blessing' of their [] studies were extremely important to investors, and, therefore, extremely misleading"). In truth, as confirmed by Dr. T. Ann Farrell, MD, Director of the Division of Non-Malignant Hematology, during pre-NDA meetings the FDA expressly rejected "[FibroGen's] proposed [non-inferiority margin] of 1.3" because "it was defined [by FibroGen] after the results of the study were known" (*i.e.*, *post hoc*, ¶¶55, 152), and in fact told FibroGen that the FDA "had a goal of 1.25"—not 1.3[11] *(see e.g.,* ¶¶55, 110, 152). Furthermore, and significantly, under the FDA prespecified sensitivity analyses that FibroGen never disclosed to investors—and which were disclosed by the FDA for the first time during the AdCom—Roxadustat's hazard ratio margins were significantly worse and in fact greatly exceeded 1.25 and 1.3 in every key endpoint. ¶¶175, 183, 204, 228.

In their briefs, Defendants claim these statements were not false because FibroGen told investors that it had not reached agreement with the FDA on any non-inferiority threshold. *See* DM at 12; YM at 5. However, as the Complaint clearly alleges, both Defendants' statements that Roxadustat's safety results satisfied the 1.3 margin the FDA purportedly "commonly applied"—and that FibroGen purportedly had no agreement with the FDA about what the non-inferiority threshold should be—were materially false and misleading because they omitted the critical fact that the reason for the lack of agreement was that the FDA had emphatically rejected 1.3 as invalid and had stated all along that its goal was an upper bound of 1.25. *See* ¶229; *Khoja,* 899 F.3d at 1010 ("[O]nce Orexigen chose to tout the apparently positive 25 percent interim results, Orexigen had the obligation also to disclose that they were likely unreliable"); *Omnicare, Inc. v. Laborers Dist. Council Const. Ind. Pen. Fund*, 575 U.S. 175, 135 S.Ct. 1318, 1331 (2015) ("[L]iteral accuracy is not enough: an issuer must as well desist from misleading investors by saying one thing

[11] Dr. Ellis Unger's "1.3 is reasonable" statement that came before Dr. Farrell's revelation is trivial since as Dr. Unger in the same breath admitted, "I wasn't involved in the discussions because this division wasn't within my office at the time" and "It's hard for me to say what I might have done, especially now that we have the data in front of us; so it's not a great answer." DX XX at 195.

and holding back another.").

Defendants' attempt at a fraud by hindsight argument by referring to Dr. Farrell's statement as "long after the challenged statements" fails. DM at 13. As Dr. Farrell clearly stated, she was personally "involved in the negotiations" at the time they occurred, and described "what we discussed during those meetings." DX XX at 196[12]; *MannKind*, 835 F. Supp. 2d at 809–10 (statements "that the FDA had accepted, or blessed, or agreed to the Defendants' [] methodology—which are shown to be false by a later revelation demonstrating that the FDA had not, in fact, done any such thing—do not constitute 'fraud-by-hindsight,' as Defendants repeatedly allege").

3. Defendants Falsely Assured Investors That "There's No Warrant [For A] Black Box" And That There Was A "High Level Of Conviction On The Overall [NDA] Submission"

Knowing that the warning label given to Roxadustat was of paramount importance to investors, and in direct response to analyst questions on the subject, Defendants repeatedly and falsely represented that the Company had "the very best chance basically to have a label without a 'Black Box'" due to its "excellent," "extremely clean" data. *See e.g.,* ¶¶160, 165, 184, 187, 192, 196, 201. Defendants also consistently averred that they "had all the guidance from the FDA [they] needed to put together a winning submission" for Roxadustat; that "interaction with the FDA was positive," allowing the NDA submission to progress as expected; and that "FibroGen's NDA submission was complete and transparent."[13] *See e.g.,* ¶¶145, 148, 167, 169, 178, 179, 198, 199, 207, 208, 212. Even after FibroGen shocked investors by announcing that an AdCom meeting would be held, Defendants assured investors as to the "completeness of the NDA." ¶¶218, 219,

[12] Defendants also attempt to discredit Dr. Farrell as a mere "reviewer." DM at 13. As Dr. Farrell notes, in addition to being a hematologist and medical oncologist, she is the Division Director of the Division of Non-Malignant Hematology in the Office of Cardiology, Hematology, Nephrology, and Endocrinology. DX XX at 16.

[13] Defendant Yu incorrectly argues that the CAC misrepresents the documents it purports to quote. *See* YM at 5. In response to the analyst question on May 9, 2019 regarding FibroGen avoiding a black box, Yu responded that: "[B]ased on what we have seen, we are pretty comfortable with safety. The adjudicated composite safety endpoint was something that we have discussed with the FDA." ¶160. On May 7, 2020, Yu touted, "[w]e like the hand that we have and expect the product label to reflect the results of clinical trials on our compound." ¶189. Absolutely nothing is being misrepresented. Moreover, Defendant Yu cannot downplay her March 2, 2020 "clean label safety for non-dialysis" statement, as this determined the Company's ability to access the untapped $3.5 billion market that Epogen could not because it was too unsafe for that population. ¶¶4, 42, 48.

231; *see MannKind,* 835 F. Supp. 2d at 811 ("Defendants' statements concerning 'approval'…by the FDA 'necessarily implied that there would be no serious impediments to timely FDA approval.' The natural effect of these statements would be to create the impression for investors that… 'it was in the bag'").

These statements were patently false. Defendants knew that the undisclosed prespecified analyses showed that Roxadustat was significantly less safe than Epogen, which already had the "Black Box" warning. Furthermore, as the FDA would ultimately reveal at the AdCom, Defendants knew that the prespecified analyses showed that Roxadustat was too unsafe to be approved at all, regardless of any "Black Box" warning. Additionally, Plaintiffs' CWs confirmed that, by no later than the fall of 2020, the FDA had clearly indicated to the Company that at the very least, Roxadustat's alarming safety issues would undoubtedly require a "Black Box." ¶¶128-31. Despite this, Defendants continued to falsely represent that their discussions with the FDA about the label were going well while concealing that the exact opposite was true. ¶¶201, 205, 208. *In re BioMarin Pharm. Inc. Sec. Litig.,* 2022 WL 164299, at *9 (N.D. Cal. Jan. 6, 2022) (citing *Warshaw v. Xoma Corp.* 74 F.3d 955, 957 (9th Cir. 1996)) (finding falsity where FDA ultimately denied approval based on the disappointing Phase III data because contrary to the defendants' representations, the defendants knew that there was "no chance" of expedited FDA approval).

Defendants cannot escape liability by arguing that the fate of Roxadustat's label was "in the hands of the FDA."[14] *See* YM at 1, 5; DM at 12. Defendants knew, but failed to disclose, that they had manipulated all nine safety analyses *post hoc* to make Roxadustat look significantly safer than it really was, thus giving the market the false impression that a Black Box would not be warranted and FDA approval was near certain. *Arena*, 840 F.3d at 707–08 ("once defendants chose to tout [drug's] likely approval by referencing allegedly positive…studies, they were bound to do so in a manner that wouldn't mislead investors"); *BioMarin,* 2022 WL 164299, at *10 (FDA approval statements were "misleading because [the Company] was allegedly aware of concrete risks that

[14] Defendants misleadingly argue that Defendant Conterno told the market that his base case was black box, failing to mention that he first stated that his base case was a broad label. DM at 12. In response to Dr. Porges' inquiry, Defendant Conterno stated: "base case is, yes, that we have a broad label. And I think the base case for me is also that we get a black box, but we have the optionality of an upside of not be able to get one, given the data that we have." DX U at 9.

approval would be denied even as it projected that it would be granted"); *MannKind*, 835 F. Supp. 2d at 809 ("these representations are best read as a misstatement of the basic facts regarding the company's ongoing involvement with the FDA, and thus the likelihood of [the drug's] approval").

4. Defendants Falsely Stated That FibroGen Had Achieved Superiority In Efficacy Against Placebo And Epogen; "Improvement In Quality Of Life" And "Lower Transfusion Risk"

Throughout the Class Period, Defendants repeatedly overstated Roxadustat's efficacy while simultaneously concealing the Company's unfavorable clinical trial results. *See e.g.,* ¶¶142, 145, 148, 155, 163, 187, 189, 190, 201, 205, 207, 217. Defendants claimed that Roxadustat had "achieved superiority in efficacy not only against placebo but also over [Epogen]," and that Roxadustat was "so efficacious and so well tolerated, patients really like staying on our drugs." *See e.g.,* ¶¶142, 155. Additionally, Defendants touted the "efficacy benefits" of Roxadustat, including "lower transfusions" and "improvement in quality of life." *See e.g.,* ¶¶148, 163, 187, 189, 190.

These statements were materially false and misleading. As Defendants well knew, the purportedly positive Roxadustat efficacy touted by Defendants was based on their *post hoc* manipulations. *See Oklahoma Police Pension & Ret. Sys. v. LifeLock, Inc*., 780 F. App'x 480, 483 (9th Cir. 2019) ("companies mislead investors when they tout their products' capabilities but fail to disclose significant flaws that undercut those capabilities"); *Khoja,* 899 F.3d at 1010 ("once [the Company] chose to tout the apparently positive [] results, [the Company] had the obligation also to disclose that they were likely unreliable"). As Defendants admitted and as the AdCom revealed, based on the real data, Roxadustat was significantly less safe than placebo and even Epogen—causing the FDA to refuse to approve the drug, thus rendering its efficacy moot. With respect to Defendants' specific efficacy claims about reduced blood transfusions and improved quality of life, these statements were also clearly false. The FDA determined that the claimed reduction in blood transfusions versus Epogen was in fact "unclear" and likely nonexistent at the untested lower doses, ¶¶104, 146, 191, 194—and the AdCom found there was "a surprising lack of improvement in quality of life" in patients taking Roxadustat. ¶112.

Defendants' assertion that Roxadustat's "efficacy is beyond dispute" is therefore erroneous.

Particularly in the context of a drug for which the primary focus is safety due to the vulnerable patients it is meant to treat, Roxadustat's efficacy was in fact highly questionable in the eyes of the FDA and rendered completely moot by its safety issues that Defendants never disclosed. YM at 1; DM at 14. Defendants similarly miss the mark by arguing that Plaintiffs "conflate efficacy with the FDA's risk benefit analysis." DM at 14. Defendants were simply not permitted under the federal securities laws to make glowing statements about Roxadustat's "superior" efficacy while concealing numerous significant safety issues that wholly eclipsed any such claims, as evidenced by the fact that Roxadustat was never approved by the FDA.

5. Defendants' Statements Are Not Inactionable Opinions

Defendants argue that nearly every alleged false statement about the Phase 3 data was an "accurate statement of opinion" as a matter of law. Defendants are incorrect.

First, Defendants' statements were not opinions. To the contrary, Defendants released nine specific safety analyses of the Phase 3 data that they later admitted they had to completely restate due to their *post hoc* manipulations. Similarly, Defendants' claims that Roxadustat "reduced risk of MACE by 30%" in the crucial incident dialysis population; that "Phase 3 results confirmed the cardiovascular safety of [R]oxadustat"; that the manipulated analyses were "agreed [upon] with the FDA" and that "we have achieved non-inferiority" were strident and specific proclamations of fact. *See e.g.,* ¶¶158, 167, 171.[15] As Defendants' own stark admissions and the FDA's later revelations at the AdCom confirm, all of these statements were demonstrably false.

Thus, while Defendants repeatedly assert that this is a case about a mere difference of scientific opinion, that is clearly not the case. YM at 11; DM at 14. This is not a situation in which Plaintiffs disagree with how Defendants conducted the Phase 3 trials or even analyzed the Phase 3 data. Rather, this is a case in which Defendants presented manipulated Phase 3 data to investors that they falsely claimed was the real, prespecified data. That is not a difference of opinion—that

[15] *See e.g., In re QuantumScape Sec. Class Action Litig.,* 2022 WL 137729, at **15-16 (N.D. Cal. Jan. 14, 2022) (statements "that the test conditions are, as a factual matter, not 'compromised,'" that "testing showed, as a factual matter, that [products] were faster than the conventional ones on the market," and "that [company] was able to show [product] 'capable of performing under uncompromised test conditions'" were not opinions); *See In re Tesla, Inc. Sec. Litig.,* 477 F. Supp. 3d 903, 923–24 (N.D. Cal. 2020) (Chen, J.) ("a statement of opinion can be deemed misleading if it conveys facts, and this is especially so when the opinion contains highly specific facts").

is fraud. *Arena*, 840 F.3d at 709 ("It is the failure to disclose 'issues' and 'concerns' with the Rat Study and the FDA's interest in the outcome of those studies—not who was ultimately right about the underlying science—that matters. And it sure mattered to investors, who were understandably concerned by the information revealed in the FDA's 2010 briefing documents.").

Second, even if Defendants' statements could be couched as opinions, they are still false. In *Omnicare*, the Supreme Court explained that opinion statements can be actionable if they are not sincerely held, they do not "fairly align[] with the information in the issuer's possession," or they omit facts that "conflict with what a reasonable investor would take from the statement." *Omnicare,* 575 U.S. at 189-90; *see In re Intuitive Surgical Sec. Litig*., 2017 WL 4355072, at *2 (N.D. Cal. Sept. 29, 2017).[16] Defendants' statements here could not have been sincerely made given Defendants' intentional data manipulation.[17] *See* ¶¶53-55, 78, 79, 244-45. This is underscored by the fact that numerous prominent members of the medical community—such as Dr. Coyne, who personally worked for the Roxadustat trials—called out Defendants' "wildly misleading" "data doctoring," which they universally described as "falsified" data rather than any difference of opinion. ¶¶10, 96, 99; *Tesla*, 477 F. Supp. 3d at 923–24 ("many investors and analysts—in fact—did not read the tweet as a speculative statement of opinion according to the Consolidated Complaint"). Indeed, due to Defendants' data manipulations, publications of the Roxadustat data in prominent medical journals had to be retracted. ¶84. There is simply no way the Court can conclude at this stage that Defendants' "beliefs" were sincerely held.

Similarly, Defendants' argument that "no reasonable investor could be misled" by these purported "opinions" is directly belied by the stock's precipitous drop upon Defendants' revelation of the real prespecified analyses. *See* DM at 16; ¶¶89-101; 115-18; 237-43; *MannKind*, 835 F.

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[16] *See SEB Inv. Mgmt. AB v. Endo Int'l, PLC*, 351 F. Supp. 3d 874, 897 (E.D. Pa. 2018) ("[a]ffirmative statements about a drug's efficacy and safety may be actionable if the underlying clinical data contradicts or does not support them") (collecting cases).

[17] Contrary to Defendants' claims, "simply inserting the word 'believe' in front of a statement of fact does not, therefore, immunize Defendants from liability." *Todd v. STAAR Surgical Co*., 2016 WL 6699284, at **8–10 (C.D. Cal. Apr. 12, 2016); *see Intuitive*, 2017 WL 4355072, at *3 ("it is entirely plausible that a reasonable investor would find the information…rendered a statement like, '[w]e believe that [product] continues to be a safe and effective surgical method" materially misleading'").

Supp. 2d at 812 ("[a]s evidenced by the stock's precipitous drop following the 2011 [FDA non-approval], Defendants' representations concerning [] chances of FDA approval and the intricacies of the process were the essential underpinning of the company's share price").

Third, Defendants also contend that the alleged statements of opinion are not misleading because AZN also published them, but this argument fails. DM at 15. FibroGen's agreement with AZN expressly designated FibroGen as being in charge of the regulatory process, including the NDA, and as "hav[ing] primary responsibility for interactions with [the FDA]." ¶¶43-44, 244. Moreover, as Plaintiffs' CWs confirmed—who were all former high-ranking employees of AZN directly involved in the Roxadustat venture—FibroGen had exclusive control over the Roxadustat clinical trials, such that the *post hoc* changes to the data were made by FibroGen's most senior officers alone and were unknown to AZN. ¶¶121-25; 250-51. Indeed, the former high-level AZN employees uniformly recounted that the process of submitting the Roxadustat data to the FDA "was all driven by FibroGen"; trying to obtain information about the data from FibroGen was a "herculean task"; and "we always felt like there was more data they weren't sharing." *Id*.

6. Defendants' Statements Are Not Mere "Puffery"

Defendants' argument that their statements about the Roxadustat data being "extremely clean, "compelling," "positive" and "strong" were mere puffery fails. DM at 19-20. Aside from the fact that Roxadustat was the Company's most critical drug responsible for nearly all of FibroGen's revenues, and that investors were vocally "hyper-focused" on every statement Defendants made about the crucial Phase 3 data, Defendants falsely claimed their statements were supported by the real, prespecified data when in fact all nine reported safety analyses of the data had been falsified. This is not "puffery." *See Mulligan v. Impax Lab'ys, Inc.,* 36 F. Supp. 3d 942, 966 (N.D. Cal. 2014) (Chen, J.) (courts do not "assess the statements … in a vacuum, plucking the statements out of their context to determine whether the words, taken *per se*, are sufficiently vague so as to constitute puffery"); *Union Asset Mgmt. Holding AG v. SanDisk LLC,* 2017 WL 3097184, at *1 (N.D. Cal. June 22, 2017) ("But the statements weren't made in the abstract. They were made in a particular context that could reasonably have led investors to rely on their accuracy and

completeness"). Courts have repeatedly rejected "puffery" arguments about similar statements.[18] Moreover, the fact that these statements were clearly material to investors is evidenced by the market's universal outrage, and the massive stock price declines, when the truth was exposed. *See No. 84 Emp'r-Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 935 (9th Cir. 2003) (stock price drop "supports a finding of materiality"); *Khoja,* 899 F.3d at 1012–13 ("Because such violations might—and allegedly did—impact the financial health of Orexigen, that information was likely material to reasonable investors. Ultimately, a jury should assess materiality as a question of fact.").

7. The PSLRA Safe Harbor Does Not Shield Defendants From Liability

Defendants also assert that certain statements (*see* DM at 20; YM at 3-6) are protected by the PSLRA's "safe harbor," which protects only wholly forward-looking statements that are either accompanied by meaningful cautionary language or made without actual knowledge of their propensity to mislead. 15 U.S.C. § 78u-5. This argument fails.

As an initial matter, the statements Defendants challenge—*e.g.*, that Roxadustat "met the safety standards"; "based on what we have seen, we are pretty comfortable with safety"; and "we had all the guidance from the FDA we needed to put together a winning submission"—are misstatements of past or current fact, and thus ineligible for safe harbor protection. ¶¶153, 160, 178. *See Immune*, 375 F. Supp. 2d at 1034 ("To the extent that Agouron highlights Study 806 results that were already available at the time, such statements are not forward-looking and therefore are not eligible for such safe harbor protection.").[19]

Even if Defendants' statements could be deemed forward-looking, Defendants' boilerplate

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[18] *See e.g., BioMarin*, 2022 WL 164299, at *12 ("statements were not empty opinions similar to puffery, they were undergirded by factual assertions such as timelines for approval"); *Bos. Ret. Sys. v. Uber Techs., Inc.,* 2020 WL 4569846, at *7 (N.D. Cal. Aug. 7, 2020) ("telling investors FDA approval was 'going fine' when the company knew approval would never come was not puffery"); *Rihn v. Acadia Pharms. Inc*., 2016 WL 5076147, at *7 (S.D. Cal. Sept. 19, 2016) ("Defendants' statements were factual representations regarding Acadia's preparedness for the NDA submission and were material"); *STAAR Surgical*, 2016 WL 6699284, at *6 (statement that "we are extremely pleased with the panel's recommendation and vote of confidence and look forward to working with the FDA staff to complete review of the ICL" was false due to "Defendants' omission of facts suggesting a possible delay in [regulatory] approval.").

[19] *See also Acadia*, 2016 WL 5076147, at **6-7 ("'on track' assurances were representations about the *current* state of affairs with respect to the NDA process") (emphasis included).

warnings about the risk of FDA non-approval were not "meaningful" because Defendants nowhere warned investors that they had manipulated all nine analyses of the Roxadustat safety data *post hoc* to make the drug look much safer than it was.[20] *BioMarin*, 2022 WL 164299, at *8 (warnings geared toward "general concerns," such as changes in FDA rules, failed to discredit specific false statements about clinical trial data and FDA approval); *MannKind*, 835 F. Supp. 2d at 817 ("boilerplate" warnings "concerning the risks inherent in [the FDA approval] process" insufficient to immunize false statements about interactions with the FDA).

Moreover, the Complaint adequately alleges that Defendants knew these statements were misleading when made, and thus the safe harbor does not apply. *See supra* at 15-17. It is undisputed that Defendants had the real prespecified analyses in hand from day one of the Class Period, which completely undercuts every positive claim they made about the Phase 3 safety data. Defendants thus unquestionably knew facts that materially increased "the risk of non-approval or delayed approval based on the FDA's concerns" and actions. *Arena*, 840 F.3d at 707-08; *BioMarin,* 2022 WL 164299, at *8 (statements that defendants "had been 'quite collaborative' with the FDA, were in a 'mesh' with them, and they anticipated the inspection to occur on the date previously set" not insulated by safe harbor where "defendants knew the truth was allegedly otherwise").

B. The Complaint Adequately Alleges A Strong Inference Of Scienter

Scienter is "a mental state that not only covers intent to deceive, manipulate, or defraud, but also deliberate recklessness." *Arena*, 840 F.3d at 705. A "strong inference" "need not be irrefutable … or even the most plausible," and no "smoking-gun" is required. *Tellabs*, 551 U.S. at 324-26. The test is simply "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Id*. at 322-23 (emphasis in original). Courts assess the allegations "holistically as required by *Tellabs*, … with a practical and common-sense perspective." *Robb v. Fitbit Inc*., 2017 WL 219673, at *8 (N.D. Cal. Jan. 19, 2017). The Complaint satisfies this standard.

Defendants' scienter here is self-evident. Defendants admitted in their April 6, 2021 press

[20] For example, Defendants point to vague warnings such as how the FDA "may change their approvability criteria" or that approval may be delayed (DM at 16 n.13)—none of which warned investors that Roxadustat's data was not based on "prespecified" analyses agreed upon with the FDA, but rather Defendants' own *post hoc* manipulations of those analyses.

release that they made *post-hoc* manipulations to all nine analyses of the Phase 3 data for Roxadustat—the Company's most critical drug that represented nearly 100% of its revenues—all of which made the drug appear significantly safer than it actually was. Defendants then shamelessly touted that falsified data to the market for over two years, proclaiming how "compelling" and "outstanding" it was on each and every investor call as FibroGen's stock price surged by over 46% and Defendants cashed in on over $42 million in insider sales. Significantly, the nature of these manipulations—including that they were applied to nine out of nine critical safety analyses and tipped heavily in favor of Roxadustat, especially for the most lucrative patient populations—confirmed that they did not happen by chance and could not have been implemented by some rogue employee. Rather, they had to have been orchestrated by the Company's most senior officers.

This is therefore not a case in which Defendants can claim they were uninvolved in or uninformed about the Roxadustat NDA—in fact, aside from Roxadustat comprising virtually all of FibroGen's revenues during the Class Period, Defendants admitted that they personally participated in pre-NDA meetings with the FDA. Nor is it plausible that Defendants were unaware of the real, prespecified analyses upon which FDA approval of their most crucial drug depended. Indeed, Defendants admitted in the April 6, 2021 release that they had the prespecified analyses in hand all along, as they had included those analyses in the NDA—but had misleadingly buried them by presenting the manipulated data as the real data, forcing them to rush to "clarify" the issue with the FDA once their fraud became apparent. Defendants' stark admission that they manipulated the Phase 3 safety data for what was unquestionably their most critical drug—and then falsely touted that manipulated data for over two years—easily establishes scienter. *Immune Response*, 375 F. Supp. 2d at 1022 ("[T]he fact that the defendants published statements [about clinical trial results] when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter."); *BioMarin*, 2022 WL 164299, at *14 (finding scienter: "[p]ut simply, the defendants allegedly told the market things that were allegedly not true and that [they] must have known were not true by their nature"); *MannKind*, 835 F. Supp. 2d at 815 (finding scienter "based on the falsity of the statements and Defendants' access to information contradicting those statements," particularly where "the company's interactions with the FDA" were "absolutely

integral to [its] success").

While nothing more is necessary, myriad additional facts raise a strong inference of scienter.

First, Defendants repeatedly made specific, strong responses to analysts' direct questions confirming that the data was sanctioned by the FDA—when Defendants knew (and would later admit) that the exact opposite was true. ¶¶247-248. *See In re Qualcomm Inc. Sec. Litig.*, 2019 WL 1239301, at *11 (S.D. Cal. Mar. 18, 2019) ("specific [statements] … in response to questions from analysts and investors" contributed to a strong scienter inference).

Second, prominent scientific and financial community members universally concluded that Defendants' manipulations were intentional in nature. For example, these commentators excoriated FibroGen's management for perpetrating the "worst case of data manipulation in years"; "touting false heart safety data . . . for at least two years"; "admit[ting] to presenting Roxadustat data to make the anemia drug look safer than it is"; and concluded that Defendants' admissions "will negatively affect management's credibility" given that "[t]he fact that all nine analyses" were manipulated "raises the suspicion" that the manipulations were orchestrated by the Company's most senior officers, as "this could [not have] happen[ed] accidentally." ¶¶239-42.[21] The fact that these sophisticated commenters—all of whom were well-versed with respect to how clinical trials are run and how clinical trial data should be reported—unanimously concluded that Defendants must have intentionally manipulated the data bolsters an inference of scienter.

Third, as set forth above, Roxadustat was FibroGen's single most important drug, and thus indisputably its core operation, with the Company deriving "substantially all" of its revenue from milestone payments for Roxadustat. ¶246. As this Court has explicitly held, when "significantly more than half" of a company's revenue derives from an operation, the "operation is prominent enough that it would be absurd to suggest that top management was unaware of" issues with that operation. *Azar v. Yelp, Inc.*, 2018 WL 6182756, at *20-21 (N.D. Cal. Nov. 27, 2018) (Chen, J.) (collecting cases); *see also MannKind*, 835 F. Supp. 2d at 815 (finding scienter when "interactions

[21] Unlike *In re Wet Seal, Inc. Sec. Litig.*, 518 F. Supp. 2d 1148, 1172-73 (C.D. Cal. 2007), where "no specific facts to corroborate [] reliability" were alleged, Plaintiffs do not parrot "[c]onclusory allegations" from newspapers (DM at 27)—rather, Plaintiffs have cited multiple renowned, sophisticated analysts and experts by name, such as Dr. Daniel Coyne, a nephrologist who personally had worked as a site investigator in the Roxadustat trials. ¶10.

with the FDA regarding [drug] approval were absolutely integral to the company's success"); *Impax*, 36 F. Supp. 3d at 970 ("absurd" that "CEO and CFO of a pharmaceutical company would be unaware" of the FDA's concerns at "the heart of a company whose main business is manufacturing pharmaceuticals").[22]

Fourth, the FDA, not Defendants, revealed the full truth about the negative safety profile for Roxadustat that doomed approval. Specifically, even after Defendants' April 2021 admissions—which themselves were forced by the FDA unexpectedly calling for an AdCom late in the regulatory process—Defendants still did not disclose the results of crucial FDA prespecified sensitivity analyses showing that Roxadustat was statistically less safe than placebo and Epogen in all studied populations. ¶249. "Defendants' own response to the issue contributes" to a "cogent and compelling inference that [they] elected not to disclose the reports of adverse events not because [they] believed they were meaningless but because [they] understood their likely effect on the market." *Arena*, 840 F.3d at 708; *see also Brown v. China Integrated Energy, Inc.*, 875 F. Supp. 2d 1096, 1124 (C.D. Cal. 2012) ("concealment is strongly indicative of scienter").

Fifth, Plaintiffs' CWs confirmed Defendants' first-hand knowledge and control of the Roxadustat safety data, their focus on the market response to that data, their misrepresentation of the true data, and their contemporaneous assurances to investors that a "Black Box" was not warranted when the FDA had in fact already informed them that such a warning would be required. ¶¶250-51.[23] Taken together, these accounts establish that Defendants controlled the clinical trial data and the NDA submission, and were aware starting in November 2020 that the FDA had identified red flags that seriously jeopardized FDA approval and made clear that a "Black Box" warning was likely. ¶¶121, 129, 130; *Hatamian v. Advanced Micro Devices, Inc.*, 87 F. Supp. 3d

[22] Moreover, Defendant Conterno had been preparing in-depth for the AdCom for about a year prior to the April 6, 2021 press release, so it defies credulity that he could have been unaware of the manipulations to data he extensively touted until April 2021. ¶87.

[23] Contrary to Defendants' assertions, the CAC pleaded the CW accounts with particularity, as it specified the titles and work histories of the high ranking CWs at great length. ¶¶121-23. *See Impax*, 36 F. Supp. 3d at 963 (plaintiffs who "number each witness and describe his or her job description and responsibilities" describe CWs with "sufficient particularity"). The CAC also does not lack allegations of "direct interaction" (DM at 22); it alleges CW 3, a Global Vice President at FibroGen partner AstraZeneca, attended "boardroom meetings" where "Defendant Yu presented data from FibroGen slide decks." ¶¶124, 251.

1149, 1163 (N.D. Cal. 2015) (CW statements well pleaded where "the CWs corroborate one another's statements").[24]

Sixth, as referenced above, the Individual Defendants engaged in highly significant, coordinated insider trading, and received substantial compensation that was directly tied to Roxadustat performance goals. ¶¶253-54. Defendants not only concede that Neff sold over fifty thousand more shares during the Class Period than the eight months before (DM at 25)—packing sales of 638,448 shares worth more than $32 million into these next eight months (¶253)—but their own chart (ECF No. 110, Appendix D) confirms that he furiously unloaded more than 317,000 shares worth more than $13 million in the three months after FibroGen's May 9, 2019 top-line announcement of the doctored MACE safety data, and at the same time Defendants were repeatedly asserting that the Phase 3 data had shown "compelling evidence confirming Roxadustat's cardiovascular safety to support our regulatory filings." ¶57; *BioMarin*, 2022 WL 164299, at *14 (stock sales of $23 million in case involving doomed drug "help[] contribute to an inference of scienter"). Defendants also do not dispute that Defendant Cotroneo sold nearly 40% of his total vested securities worth $7 million, with the largest sale coming just weeks after Defendants' adamant denial of any issues with Roxadustat's trial data.[25] ¶253. *See Yelp*, 2018 WL 6182756, at *19 ("temporal proximity between the sales and the release of" positive information "could support an inference of scienter"). Defendant Yu also reaped over $10 million in stock and option awards directly tied to completing the manipulated Roxadustat MACE safety analysis and the submission of the misleading Roxadustat NDA to the FDA, on top of a $1.4 million raise and selling $2 million worth of stock during the Class Period. ¶¶253-54. *See Am. W. Holding Corp.,* 320 F.3d at 944 (scienter where executives were "motivated to inflate [company's] financial results and stock prices

[24] *See also In re Quality Sys., Inc. Sec. Litig.* 865 F.3d 1130, 1145 (9th Cir. 2017) (taken together, CW accounts showed that defendants had "actual access" to information central to the case and thereby "raise[d] a strong inference of scienter"); *Impax*, 36 F. Supp. 3d at 963 ("Plaintiffs use the confidential witnesses [] to demonstrate the pervasive and systematic nature of [company's] problems" from which "the falsity of Defendants' statements [] may be inferred").

[25] Defendant Conterno's June 2020 share purchases do not weigh against scienter. As a new employee FibroGen required him to buy as "CEO to achieve and maintain ownership of shares valued at five times his base salary". FibroGen 2021 Proxy at 40. Defendant Eisner was also required to meet minimum stock ownership amounts, so his lack of sales is irrelevant. *Id.* Available at https://fibrogen.gcs-web.com/node/11831/html.

because their eligibility for stock options and executive bonuses were based principally on the company's financial performance"); *Evanston Police Pension Fund v. McKesson Corp.*, 411 F. Supp. 3d 580, 603 (N.D. Cal. 2019) (same).[26]

Finally, Defendant Yu's abrupt resignation less than one month before the PDUFA date of December 20, 2020 for Roxadustat—and less than four months before FibroGen's revelation of the manipulated analyses—is highly suspicious and indicative of scienter. ¶258. *See Shenwick v. Twitter, Inc.*, 282 F. Supp. 3d 1115, 1148 (N.D. Cal. 2017) (departure of senior executives in weeks before and after key disclosures probative of scienter).[27]

C. Defendants' "Straw Man" Challenges To Scienter Fail

Defendants' argument that Plaintiffs' scienter allegations are illogical because there was no reason for them to invest in a drug they knew would not receive FDA approval "attacks a straw man": Plaintiffs' "allegations are not that the [D]efendants were *convinced* the FDA would deny approval, it is that they withheld important *warning signs* from the market." *BioMarin*, 2022 WL 164299, at *13 (emphasis in original). Plaintiffs here do not allege that Defendants believed during the Class Period that the FDA's rejection of Roxadustat was a foregone conclusion. To the contrary, the CAC pleads that Defendants touted their manipulated data while concealing the true prespecified analyses from investors and the FDA in an effort to both inflate FibroGen's stock price and obtain FDA approval for an unsafe drug. As such, Plaintiffs "have alleged a 'cogent and powerful' inference of scienter." *Id.* In contrast, the competing inference Defendants ask the Court to make—their "good faith" belief that Roxadustat was safe—is not only completely implausible, but wholly belied by the fact that Defendants manipulated all nine crucial Phase 3 safety analyses

[26] While Defendants assert these sales are immunized by 10b5-1 trading plans, sales pursuant to 10b5-1 trading plans do "not preclude a finding of fraud" if "at the time the plans were adopted … the individual defendants were allegedly aware" that their statements were false. *Yelp*, 2018 WL 6182756, at *18. Moreover, conspicuously, nowhere do Defendants divulge the details of their 10b5-1 plans. "Without reviewing [the] actual trading plan," the Court cannot conclude such sales negate scienter. *Id*. In any event, even if the trades were pre-planned, "concealing [] negative information before the sale and setting the sale to occur prior to the PDUFA date were discretionary choices, so it is sufficient at the pleadings stage to contribute to the plausibility of the scienter allegations." *BioMarin*, 2022 WL 164299, at *14.

[27] Yu's brief stint as a consultant does not negate scienter (YM at 13); an "innocent inference is undermined by allegations that" FibroGen "continued to struggle with transparency after the initial resignation[]." *In re WageWorks Inc., Sec. Litig.*, 2020 WL 2896547, at *7 (N.D. Cal. June 1, 2020).

to make the drug look safer than it was. Indeed, Defendants can offer no plausible non-fraudulent explanation for why they manipulated the Roxadustat data, or why they wholly concealed the real prespecified analyses upon which FDA approval depended from investors for over two years.

In support of their argument, Defendants hang their hats on decisions that are at best inapposite, and at worst, the opposite of what they contend. For example, *Rigel* does not support an inference of good faith. DM at 22. Rather, in stark contrast to FibroGen, those defendants did not "misrepresent[] their own statistical methodology, analysis, and conclusions," and the court there even expressly warned that a "post-hoc adaptation of a statistical method could raise concerns regarding [] even fraud," as "otherwise someone"—like Defendants here—"can manipulate the unblinded data to obtain a favorable result." 697 F.3d at 878-79.[28] Similarly, *Nguyen v. Endologix, Inc.*, 962 F.3d, 405, 415 (9th Cir. 2020) is inapplicable. Soon after receiving data showing increased adverse effects, "defendants disclosed that information"—unlike Defendants here, who concealed it for two years—and the plaintiff there failed to demonstrate that defendants should have viewed the data as sufficiently problematic to have made FDA approval less likely. *Id.* at 419.

Thus, try as they may, Defendants cannot get the *Rigel* or *Endologix* shoe to fit, nor escape the on-point decision in *Arena*. There, the Ninth Circuit found that when defendants chose to claim "all of the data was running in [the drug's] favor" for FDA approval, they misled investors by withholding the results of a rat study showing the drug's risk of cancer. The defendants' withholding of these results, the later disclosure of which caused a 40% stock drop, made "quite clear that Arena understood that the FDA did not entirely agree with Arena's views of the Rat Study," thus establishing scienter. *Id.* at 707-08.[29]

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[28] While Defendants cite *Matrixx*, 563 U.S. at 44 for the proposition that "there is no requirement [] to disclose all material information," the Supreme Court there specifically found that a company that publicly stated that the safety and efficacy of its drug had "been well established" but failed to disclose information about a lack of studies conducted to disprove adverse consequences, had misled investors. *Id*. *See also Rigel*, 697 F.3d at 881, n.10 (distinguishing *Matrixx* because in *Rigel*, unlike here, "the omitted information did not contradict, or render misleading, the original reports of the top-lines results"). *Patel v. Seattle Genetics, Inc.*, 2018 WL 2359137, at *9 (W.D. Wash. May 24, 2018) is also no aide to Defendants, who, by reporting manipulated data, hardly were "cooperating with the FDA," particularly when they needed to "clarify" the issue with the FDA precisely because of their manipulated data.

[29] The *Endologix* court even specifically distinguished *Arena*, because Arena (like Defendants here)

D. This Is Not A "Group Pleading" Case

Defendants' last-ditch effort is to assert that the CAC only makes group pleading allegations. DM at 26. But there is no group pleading where, as here, Plaintiffs allege the Individual Defendants "signed SEC filings with material and misleading information," and where executives "whose general responsibilities would have afforded [] knowledge" regarding the falsity of their statements about Roxadustat. *In re Wells Fargo & Co. S'holder Deriv. Litig.*, 282 F. Supp. 3d 1074, 1095 (N.D. Cal. 2017). In any event, Defendants' contention that the CAC is "essentially silent as to the state of mind of any Individual Defendant" (DM at 28) is just wrong. The CAC is loud and clear in amply alleging every false and misleading statement that each Individual Defendant (and Neff) made, and that each Defendant had access to the very safety data that they manipulated and falsely touted to investors.[30] *See*, *e.g.*, ECF No. 91-2.

E. The Complaint Adequately Alleges Section 20(a) Claims

As Lead Plaintiffs have stated a Section 10(b) against Defendants, Plaintiffs' Section 20(a) claim should be upheld as well. *See MannKind,* 835 F. Supp. 2d at 820.

V. CONCLUSION

For all of these reasons, Defendants' motions to dismiss should be denied.[31]

Dated: March 4, 2022

Respectfully submitted,

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had touted that "the results of the study made it confident that the FDA would approve the drug," while concealing the study that was "*the* sticking point with the FDA." *Id*. at 418. Defendants also contend that their alleged false statements must be considered in light of regulatory approvals of Roxadustat in other jurisdictions (DM at 23), but as these other jurisdictions have considerably different study requirements and criteria than the FDA and utilized different data sets, there is no reason to think that approval in other countries would lead to approval here. What matters is whether the data would satisfy the FDA's requirements or not.

[30] Defendants also concede (by not disputing) the CAC sufficiently alleges scienter for FibroGen. *See China Integrated*, 875 F. Supp. 2d at 1122 (finding inference of corporate scienter "[e]ven absent detailed allegations about the level of detailed knowledge [of] corporate officers").

[31] If the Court grants the motion as to any defendant, Plaintiffs respectfully request leave to amend. *See Eminence Capital, LLC v. Aspeon, Inc*., 316 F.3d 1048, 1052 (9th Cir. 2003).

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on March 4, 2022, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel or parties of record.

/s/ Lester R. Hooker
Lester R. Hooker